



Practitioner's Docket No.

2331/124

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

OR

In re application of: Bevilacqua, M., et al.

Application No.: 10/772,783

Group No.: N/A

Filed: February 5, 2004

Examiner: N/A

For: Identification, Monitoring and Treatment of Disease and Characterization of Biological Condition  
Using Gene Expression Profiles

Commissioner for Patents  
P.O. Box 1450, Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. SECTION 1.97(b))

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CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

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Date: August 25, 2004

Signature



Barbara J. Carter, Ph.D.

(type or print name of person certifying)

*NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).*

*NOTE: The "filing date of a national application" under 37 C.F.R. section 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. section 1.53(b) as "the date on which: (1) A specification containing a description pursuant to section 1.71 and at least one claim pursuant to section 1.75; and (2) any drawing required by section 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by section 1.41." 37 C.F.R. section 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. section 371(c) within the periods set forth in section 1.494 or section 1.495. 35 U.S.C. section 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. section 1.97(b)(2).*

## **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

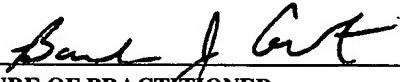
*NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*

*NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

*NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

*NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirement (37 C.F.R. section 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. section 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

***WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. section 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).***



**SIGNATURE OF PRACTITIONER**

Reg. No. 52,703

Barbara J. Carter, Ph.D.

(type or print name of practitioner)

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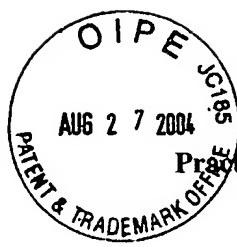
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Boston, MA 02110

02331/00124 327562.1



Practitioner's Docket No.

2331/124

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_  
for \_\_\_\_\_ Inventor(s)  
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Bevilacqua, M., et al.

Application No.: 10/772,783 Group No.: N/A  
Filed: February 5, 2004 Examiner: N/A  
For: Identification, Monitoring and Treatment of Disease and Characterization of Biological Condition  
Using Gene Expression Profiles

Commissioner for Patents  
P.O. Box 1450, Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 12)

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CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

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Date: August 25, 2004

\*WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

## INFORMATION DISCLOSURE STATEMENT

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### **List of Sections Forming Part of This Supplemental Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

*(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)*

1. Preliminary Statements
2. Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. Statement as to Information Not Found in Patents or Publications
4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. Cumulative Patents or Publications
6. Copies of Listed Information Items Accompanying This Statement
7. Concise Explanation of Non-English Language Listed Information Items
  - 7A. EPO Search Report
  - 7B. English Language Version of EPO Search Report
8. Translation(s) of Non-English Language Documents
9. Concise Explanation of English Language Listed Information Items (Optional)
10. Identification of Person(s) Making This Information Disclosure Statement

*(complete the following, if appropriate)*

Sections , respectively, have been continued on ADDED PAGE(S).

**NOTE :**"Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

## **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



**FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Bevilacqua, M., et al. Attorney Docket: 2331/124  
 Serial No: 10/772,783 Art Group Unit: N/A  
 Date Filed: February 5, 2004 Examiner Name: N/A  
 Invention: Identification, Monitoring and Treatment of Disease and Characterization of Biological Condition Using Gene Expression Profiles

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AA	5,643,765	07/01/1997	Willey	435/91.2
	AB	5,696,130	12/09/1997	Jones, et al.	514/291
	AC	5,811,231	09/22/1998	Farr, et al.	435/6
	AD	5,846,720	12/08/1998	Foulkes, et al.	435/6
	AE	5,866,330	02/02/1999	Kinzier, et al.	435/6
	AF	5,955,269	09/21/1999	Ghai, et al.	435/6
	AG	5,968,784	10/19/1999	Spinella, et al.	435/91.1
	AH	5,994,076	11/30/1999	Chenchik, et al.	435/6
	AI	6,132,969	10/17/2000	Stoughton, et al.	435/6
	AJ	6,146,828	11/14/2000	Lapidus, et al.	435/6
	AK	6,150,169	11/21/2000	Smith, et al.	435/455
	AL	6,165,709	12/26/2000	Friend, et al.	435/6
	AM	6,185,561	02/06/2001	Balaban et al.	707/6
	AN	6,203,987 B1	03/20/2001	Friend, et al.	435/6
	AO	6,203,998 B1	02/20/2001	Kambara, et al.	435/6
	AP	6,218,122 B1	04/17/2001	Friend, et al.	435/6
	AQ	6,222,093 B1	04/24/2001	Marton, et al.	800/3
	AR	6,232,065	05/15/2001	Robinson et al.	435/6
	AS	6,245,517	06/12/2001	Chen, et al.	435/6
	AT	0012932	01/31/2002	Wang	435/6
	AU	0029028	10/11/2001	Danenberg, et al.	435/6
	AV	0045197	04/18/2002	Friend et al.	435/7.21
	AW	0051344	12/13/2001	Shalon, et al.	435/6
	AX	US2001/0018182	08/30/2001	Friend, et al.	435/6

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	AY	WO	94/23023	10/13/1994	Willey	CN12N 15/00
	AZ	WO	97/41261	06/11/1997	Gerdes, et al.	C12Q 1/68
	BA	WO	98/24935	06/11/1998	Ralph, D., et al.	C12Q 1/68
	BB	JP	10-261029	09/29/1998		
	BC	WO	98/24935	11/06/1998	Ralph, et al.	C12Q 1/68
	BD	WO	99/04251	01/28/1999	Binder, et al.	G01N 27/26
	BE	WO	99/44063	02/09/1999	Leighton, et al.	G01N 33/50
	BF	WO	99/46403	16/09/1999	Schweighoffer	C12Q 1/68
	BG	WO	99/54510 A2	10/28/1999	Lowe, et al.	C12Q 1/68
	BH	WO	99/54510 A3	10/28/1999	Lowe, et al.	C12Q 1/68
	BI	WO	99/11822	11/03/1999	Evans, et al.	C12Q 1/68
	BJ	WO	99/57130	11/11/1999	Prashar, et al.	C07H 21/04
	BK	WO	99/58720	11/18/1999	Scherer	C12Q 1/68
	BL	WO	00/11208	02/03/2000	Aebersold, et al.	C12Q 1/68
	BM	WO	00/22172	20/04/2000	Chenchik, et al.	C12Q 1/68
	BN	WO	00/28092	05/18/2000	Erlander, et al.	C12Q 1/68
	BO	WO	00/71756 A2	11/30/2000	Theilhaber, et al	C12Q 1/68
	BP	WO	01/11082 A2	02/15/2001	Cao, et al.	C12Q 1/68
	BQ	WO	01/12851 A2	02/22/2001	Weindruch, et al.	C12Q 1/68
	BR	WO	01/20998 A1	03/29/2001	Huang	A01N 63/00
	BS	WO	01/23614 A1	04/05/2001	Ho	C12Q 1/68
-	BT	WO	01/25473 A1	04/12/2001	Tryon, V.	C12Q 1/00
	BU	WO	01/27321 A2	04/19/2001	Van Der Krieken, et al.	C12Q 1/68
	BV	WO	01/29261 A2	04/26/2001	Larossa, et al.	C12Q 1/68
	BW	WO	01/29269 A2	04/26/2001	Chakravarti, et al.	C12Q 1/68
	BX	WO	01/30972 A2	05/03/2001	Thomas, et al.	C12N
	BY	WO	01/32928	05/10/2001		
-	BZ	WO	03/040404 A1	05/15/2003	Source Precision Medicine, Inc.	C12Q 1/00

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	CA		PE Applied Biosystems Manual, "The TaqMan™ PCR Reagent Kit Protocol", May 1996

	<b>CB</b>	Asthana, D., et al.	Differential Effects of IFN- $\gamma$ on Kidney Cell Expression of MHC Class II Molecules, Kidney Cell Associated Molecules and Their Stimulatory Capacity in Mixed Lymphocyte Kidney Cell Culture; <i>Transpl Immunol</i> , Vol. 1, Pages 282-293; 1993
	<b>CC</b>	Beasley, Ellen M., et al.	"Statistical Refinement of Primer Design Parameters," Academic Press, PCR Applications, 1999, pgs. 59-71
	<b>CD</b>	Beer, David G., et al.	"Gene-Expression Profiles Predict Survival of Patients With Lung Adenocarcinoma," <i>Nature Medicine</i> , Aug. 2002, Vol. 8, No. 8, pgs. 816-824.
	<b>CE</b>	Buchwald, D., et al.	Markers of Inflammation and Immune Activation in Chronic Fatigue and Chronic Fatigue Syndrome; <i>J Rheumatol</i> , Vol. 24, Pages 372-376; 1997
	<b>CF</b>	Cheronis, J.C., et al.	"Utility of High Precision QPCR in the Assessment of Anti-Inflammatory Drug Action," <i>Clinical Chemistry</i> , Vol. 48, No. 6, Supplement, June 2002, pg. A172.
	<b>CG</b>	Coenen, et al	"A quantitative PCR measurement of messenger RNA expression of IGF-I, IGF-II and IGFBP-5 in human skeletal muscle", <i>Growth Hormone &amp; IGF Research</i> 1999, 9, 179-186 Article No.ghir.1999.0104.
	<b>CH</b>	Cole, et al.,	"The genetics of cancer—a 3D model", <i>Nature Genetics Supplement</i> , Vol. 21, January 1999.
	<b>CI</b>	Eisenberg, et al.	"Protein Function in the Post-Genomic Era," <i>Nature</i> , Vol. 405:823-826, 15 June 2000
	<b>CJ</b>	Guan-Chiun Lee, et al	"Analysis of the Gene Family Encoding Lipases in <i>candid rugosa</i> by Competitive Reverse Transcription-PCR, <i>Applied and Environmental Microbiology</i> , Sept. 1999, pp. 3888-3895.
	<b>CK</b>	Humbert, M., et al.	Relationship Between IL-4 and IL-5 mRNA Expression and Disease Severity in Atopic Asthma; <i>Am J Respir Crit Care Med</i> , Vol. 156, Pages 704-708, 1997
	<b>CL</b>	Imai, S., et al.	High Levels of Expression of Collagenase-3 (MMP-13) in Pathological Conditions Associated with a Foreign-Body Reaction; <i>J Bone Joint Surg</i> , Vol. 80-B, Pages 701-710, July 1998
	<b>CM</b>	Jensen, et al	"Competitive reverse transcription polymerase chain reaction for quantifying pre-mRNA and mRNA of major acute phase proteins", <i>Journal of Immunological Methods</i> , 215 (1998), pp. 45-58.

	<b>CN</b>	Kim, et al.,	“Strong Feature Sets from Small Samples”, <i>Journal of Computational Biology</i> , Vol. 9, Number 1, 2002, Mary Ann Liebert, Inc. pp. 1127-146.
	<b>CO</b>	Korenberg	“Prediction of Treatment Response Using Gene Expression Profiles”, <i>Journal of Proteome Research</i> 2002, 1, 55-61.
	<b>CP</b>	Lockhart, et al.	“Genomics, Gene expression and DNA Arrays,” <i>Nature</i> , Vol. 405:827-836, 15 June 2000
	<b>CQ</b>	Loitsch, et al	“Reverse Transcription-Competitive Multiplex PCR Improves Quantification of mRNA in Clinical Samples—Application to the Low Abundance CFTR mRNA”, <i>Clinical Chemistry</i> 45:5, (1999), pp. 619-624.
	<b>CR</b>	Mangalam, et al.,	“GeneX: An open source gene expression database and integrated tool set”, <i>IBM Systems Journal</i> , (2001), 40 (2), 552-569, 79 refs. ISSN: 0018-8670.
	<b>CS</b>	Meijers-Heijboer, M.D., et al.,	“Breast Cancer after Prophylactic Bilateral Mastectomy in Women with a BRCA1 or BRCA2 Mutation”, <i>The New England Journal of Medicine</i> , Vol. 345:159-164, July 19, 2001, Number 3.
	<b>CT</b>	Ono, K., et al.	Cytokine Gene Expression After Myocardial Infarction in Rat Hearts (Possible Implication in Left Ventricular Remodeling); <i>Circulation</i> Vol. 98, Pages 149-156, July 14, 1998
	<b>CU</b>	Pandey, et al.	“Proteomics to Study Genes and Genomes,” <i>Nature</i> , Vol. 405:837-846, 15 June 2000
	<b>CV</b>	Paradis, Valerie, et al.	“Expression Profiling of Hepatocellular Carcinomas (HCC) Using a Large Scale Real-Time RT-PCR Approach: Determination of a Molecular Diagnostic Index,” <i>Hepatology</i> , Vol. 36, No. 4, Part 2, October 2002, page 302A.
	<b>CW</b>	PCT/US 00/17846	International Search Report, June 28, 1999, PCT/ISA/210.
	<b>CX</b>	Pfeffer, U.	“One-Tube RT-PCR With Sequence-Specific Primers,” <i>Methods of Molecular Biology</i> , Vol. 86, pgs. 149-151
	<b>CY</b>	Rafalski, et al.,	“New experimental and computational approaches to the analysis of gene expression”, <i>Acta Biochimica Polonica</i> , Vol. 45, No. 4/1998, 929-934.
	<b>CZ</b>	Reinke, P., et al.	“Immune Monitoring of Glucocorticoid Therapy,” <i>Ernst Schering Research Foundation Workshop</i> . Germany 2002, No. 40, pgs. 25-37.
	<b>DA</b>	Risch	“Searching for Genetic Determinants in the New Millennium,” <i>Nature</i> , Vol. 405:847-856, 15 June 2000

	<b>DB</b>	Rosenwald, M.D., et al	"The Use of Molecular Profiling to Predict Survival after Chemotherapy for Diffuse Large-B-Cell Lymphoma", <i>The New England Journal of Medicine</i> , Vol. 346:1937-1947, June 20, 2002, Number 25.
	<b>DC</b>	Roses	"Pharmacogenetics and the Practice of Medicine, " <i>Nature</i> , Vol. 405:857-865, 15 June 2000
	<b>DD</b>	Skedinger, M., et al.	Eosinophil Activity Reflects Clinical Status in Patients with Asthma Before and During a Prednisolone Course; <i>Ann Allergy Asthma Immunol</i> , Vol. 75, Pages 250-255, September 1995
	<b>DE</b>	Staunton, et al.,	"Chemosensitivity prediction by transcriptional profiling", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 98, Issue 19, 10787-10792, September 11, 2001.
	<b>DF</b>	Takahashi, et al.,	"Gene expression profiling of clear cell renal cell carcinoma: Gene identification and prognostic classification", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 98, Issue 17, 9754-9759, August 14, 2001.
	<b>DG</b>	Teague, et al	"Activation changes the spectrum but not the diversity of genes expressed by T cells", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 96, Issue 22, 12691-12696, October 26, 1999.
	<b>DH</b>	Van 't Veer, et al.,	"Gene expression profiling predicts clinical outcome of breast cancer", <i>Nature</i> , Vol. 415, January 31, 2002.
	<b>DI</b>	Vukmirovic, et al.	"Exploring Genome Space," <i>Nature</i> , Vol. 405:820-822, 15 June 2000
	<b>DJ</b>	Wiedbrauk, Danny L, et al.	"Nucleic Acid Detection Methods," <i>Molecular Methods for Virus Detection</i> , Academic Press, 1995, pgs. 1-26
	<b>DK</b>	Wittwer, Carl T., et al.	"Rapid Thermal Cycling and PCR Kinetics," Academic Press, <i>PCR Applications</i> , 1999, pgs 211-231
	<b>DL</b>	Zajchowski, et al.,	"Identification of Gene Expression Profiles That Predict the Aggressive Behavior of Breast Cancer Cells", <i>Cancer Research</i> 6, 5168-5178, July 1, 2001.
	<b>DM</b>	Zhan, et al.,	"Global Gene Expression Profiles Can be Used to Accurately Predict Chromosome 13 Deletion in Multiple Myeloma", Abstract #1553, Poster Board #-Session: 658-II
	<b>DN</b>	Zhang, et al	"A Novel Highly Reproducible Quantitative Competitive RT PCR System", <i>J. Mol. Biol</i> (1997) 274, pp. 338-352.
	<b>DO</b>	Zhang, et al.,	"Recursive partitioning for tumor classification with gene expression microarray data", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 98, Issue 12, 6730-6735, June 5, 2001.

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

#### **Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted**

**NOTE:** *"A copy of any patent, publication or other information listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120." 37 C.F.R. section 1.98(d).*

**WARNING:** *"This exception to the requirement for copies of information does not apply to information which was cited in an international application under the Patent Cooperation Treaty." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

**WARNING:** *"Information which is cited or submitted to the Office in the parent application of a file wrapper continuing application under 37 C.F.R. section 1.62 will be part of the file before the examiner and need not be resubmitted in the continuing application. Likewise, the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application and thus this information need not be resubmitted unless applicant desires the information to be printed on the patent." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

**WARNING:** *While a copy of a non-English language item of information need not be submitted, if it was previously submitted to, or cited by, the Office in a prior application, provided it is properly identified in this statement and this application relies on that earlier filing date under 35 U.S.C. 120, nevertheless, the requirement in section 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. The concise explanation must explain the relevance, as presently understood by the person designated in section 1.56(c) most knowledgeable about the content of the information. Notice of January 9, 1992, 1135 O.G. 13-25, at 20.*

**[x] This application also relies, under 35 U.S.C. section 120, on the earlier filing date of prior application SN.: 10/291,225, filed on November 8, 2002.**

The following references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application: AA-AY; BB-BS; CA-CC; CE; CG-CU; CW-CY; and DA-DO

## **Section 6. Copies of Listed Information Items Accompanying This Statement**

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

[x ]Exception(s) to above:

[ ]Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

[ ]Cumulative patents or publications identified in Section 5.

**U.S. patent citations are not included pursuant to 37 CFR 1.98 9(a)(2)(i) and 37 CFR 1.491(b), in which the USPTO waived the requirement for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.**

**Section 10. Identification of Person(s) Making This Supplemental Information Disclosure Statement**

The person making this certification is

(check each applicable item)

- (a) [ ] the inventor(s) who signs below

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**SIGNATURE OF INVENTOR**

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(type name of inventor who is signing)

- (b) [ ] an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

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**SIGNATURE OF INVENTOR**

---

(type name of inventor who is signing)

- (c) [x] the practitioner who signs below on the basis of the information:

(check each applicable item)

[ ] supplied by the inventor(s).

[ ] supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

[x] in the practitioner's file.

Barbara J. Carter

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**SIGNATURE OF PRACTITIONER**

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Barbara J. Carter, Ph.D.

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(type or print name of practitioner)

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